



SALALAH MEDICAL SUPPLIES
MANUFACTURING CO. LLC

شركة صلالة للصناعة
المستلزمات الطبية ش.م.م



Ref: GM/674/99

October 12, 1999

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DOCKETS MANAGEMENT BRANCH (HFA-305)

Food and Drug Administration
5603 Fishers Lane
Rm. 1061, Rockville, MD 20852

Docket No. 98N-0313

**Salalah Medical Supplies Manufacturing Co. LLC
Summary of Comments on U.S. FDA Proposed Rule:
Reclassification of Surgeon's and Examination Gloves**

1. Recommended Protein Limits

FDA Proposal: The recommended maximum water extractable protein level for latex medical gloves is 1200 micrograms/glove, as measured by ASTM D5712 - 95 (Modified Lowry Method) with a sensitivity limit of 300 micrograms/glove.

SMSMCO Comments: The maximum limit of water extractable protein level of 1200 micrograms is very low and if we will meet this requirement, our production cost will be higher. The existing global prices of medical gloves is very low in the past few years and additional cost of production to meet this requirement will definitely keep us out of the business. We suggest that the allowable limit must be increased to about 2500 to 3000 micrograms/glove and there are no sufficient data available to set the maximum limit of water extractable protein that will trigger allergic/hypersensitivity reactions.

2. Recommended Donning Powder Content Limits

FDA Proposal: The recommended amount of powder on latex and synthetic medical gloves is 120 mg powder/glove.

SMSMCO Comments: Setting a powder content of 120 mg powder/glove which FDA has no data to support the statement that this powder limit will reduce the number of allergic reactions is not acceptable. Besides donning powder commonly used by manufacturers are FDA approved and limiting to this level will only affect the cost, donning, tackiness and other characteristics that will adversely affect the quality and the performance characteristics of the glove. We suggest that the recommended amount of donning powder will be set at 250 - 350 mg of powder/glove.

For Salalah Medical Supplies Manufacturing Co. LLC


Ahmed Salim A. Ibrahim
General Manager

98N-0313

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MEDOK

Sultanate of Oman



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**SALALAH MEDICAL SUPPLIES
MANUFACTURING CO. LLC**

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المستلزمات الطبية ش.م.م
منطقة ريسوت الصناعية
ص ب ٣٣ - صلالة ٢١١
سلطنة عمان



To
Dockets Management Branch (HFA-305),
Food and Drug Administration,
5600 Fishers Lane,
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U.S.A.

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